

## REMARKS

Applicants respond to the Examiner's detailed September 12, 2007 Office Action with the following remarks presented according to the Examiner's communication. Claims 1 – 19 are pending in the application. Claim 2 is cancelled. Claim 1 is herewith amended. Support for the amendment can be found throughout the specification (*e.g.*, paragraph [0073] of U.S. Patent Publication No. 2004/0092988A1), drawings, and original claims. No new matter is presented by the amendment. Accordingly, applicants respectfully request entry of the amendments and reconsideration of claims 1 and 3 – 19 in light of the following remarks.

### Claim Rejections – 35 USC §102

Applicants respectfully traverse the rejection of claims 1 and 3 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,030,201 ("Palestrant"). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Palestrant does not teach all of the limitations recited by independent claim 1.

Palestrant teaches an expandable atherecotomy device including elongated cutting members "caused to bow outwardly away from the central longitudinal axis of the first catheter when the first and second opposing ends are compressed...for biting into an atheroma or blood clot material when elongated cutting members...are bowed out and rotated," See Palestrant, Col. 8, lines 38 – 62 (emphasis added). Palestrant does not teach a plurality of elastically deformable blades that can cut material in a space when the blades are not deformed, after accessing the space through a passage while the blades are deformed.

Independent claim 1 recites: "[a]n enucleation device comprising...a plurality of elastically deformable blades... where the plurality of elastically deformable blades can cut material in a space when the blades not deformed, after accessing the space through a passage while the blades are deformed." The claims are distinctive from Palestrant because Palestrant discloses cutting members that cannot cut material when not deformed, but instead can cut material only *when they are bowed* (*i.e.*, deformed). Palestrant's cutting members also do not access a space when deformed, but instead access a space while in their normal (straight)

position. Specifically, Palestrant teaches cutting members “each initially extending generally parallel to the longitudinal axis of the first catheter,” (Col. 8, lines 8 – 11) and “when...expanded by retracting tension wires, the cutting members are caused to bow outwardly, thereby causing saw tooth surfaces to contact and scrape atheromatous material or blood clot material from the walla of the blood vessel,” (Col. 10, lines 1 – 7). Therefore, only when the cutting members are caused to “bow outward” (i.e., are deformed) and rotated can the cutting members disclosed in Palestrant “bit[e] into artheroma or blood clots,” (Col. 8, lines 38 – 62). Applicants respectfully submit that claims 1 and 3 are therefore not anticipated by Palestrant. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

Applicants respectfully traverse the rejection of claims 1, 4 – 6, 11, 14, 18, and 19 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,709,697 (“Ratcliff”). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Ratcliff does not teach all of the limitations recited by claims 1, 4, 11, and 18.

Ratcliff teaches a surgical instrument for cutting tissue, including “a shaft 150...[forming] a longitudinal passageway 152 extending therethrough to receive actuator 146...[and] is provided with raised guide portions 156 and guide rails 158 to maintain the centrally disposed position of the shaft 150 within elongated tubular member 112. **This stabilization of shaft 150 is particularly important during reciprocating sliding movement of shaft 150 within elongated tubular member 112,**” Col. 4, lines 33 – 43 (emphasis added). In contrast, claims 1, 4, 11, and 18 recite a “flexible shaft.” The shaft of Ratcliff is held stable in a handle and is not flexible. Applicants respectfully submit that claims 1, 4 – 6, 11, 14, 18, and 19 are therefore not anticipated by Ratcliff. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

Applicants respectfully traverse the rejection of claims 1, 4, 8, 11, and 13 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,178,625 (“Groshong”). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of*

*California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Groshong does not teach all of the limitations recited by claims 1, 4, and 11.

Groshong teaches a catheter atherotome including “support members 34 and blade carriers 35...with the objective being to provide blade carriers and support members which are flexible to provide **outward bow-like bending** in radial planes,” Col. 7, lines 45 – 56 (emphasis added). Like Palestrant discussed above, Groshong fails to teach a plurality of blades that can cut material when not deformed, as recited in the present claims. Rather, Gorshong’s “blades” can cut material only *when bowed* (i.e., deformed). (Col. 7, line 50.) Groshong’s “blades” also do not access a space when deformed, but instead access a space while in a normal (straight) position. (Col. 7, lines 50 – 55.)

In addition, Groshong teaches only a *single* blade 52. (Col. 6, line 57.) In contrast, independent claims 1, 4, and 11 require “a plurality of elastically deformable blades.” The Office Action incorrectly characterizes support members 34 and blade carriers 35 as a plurality of deformable blades. Groshong teaches a single, “finger-nail” shaped blade 52 with a single sharpened edge 60. (Col. 6, lines 57 – 65.) Only when the support members 34 and blade carriers 35 are caused to “bow outward” (i.e., is deformed) can the blade disclosed in Groshong “excise a strip of plaque from the interior wall of [an] artery,” (Col. 7, lines 5 – 8). Applicants respectfully submit that claims 1, 4, 8, 11, and 13 are not anticipated by Groshong. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

### Claim Rejections – 35 USC §103

Applicants respectfully traverse the rejection of claims 7 and 12 under 35 U.S.C. 103(a) as being unpatentable over Ratcliff as applied to claims 4 and 11. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Claims 7 and 12 are distinct from the device and method taught by Ratcliff for the reasons stated above in the section under the heading, “Claim Rejections – 35 USC §102” because Ratcliff fails to teach all of the limitations recited in claims 4 and 11. Ratcliff fails to teach a device including a flexible shaft as required by claim 1, and in fact, teaches away from a flexible shaft by requiring a rigid shaft.

Applicants respectfully submit that claims 7 and 12 are therefore patentable over Ratcliff.

Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

Applicants respectfully traverse the rejection of claims 1, 4, 9, 11, 15, and 16 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,746,451 to Middleton (“Middleton”). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Middleton does not teach all of the limitations recited by claims 1, 4, and 11.

Middleton teaches a cavitation device including a “rotatable shaft 110 with a longitudinal axis,” and a single blade. Col. 5, lines 44 -45. Like Ratcliff and Palestrant discussed above, Middleton discloses a rigid shaft, and discloses a cutting element that can cut material in a space when the blade is deformed, after accessing the space when the cutting element is not deformed — directly opposite the elements recited in the present claims. In contrast to Middleton’s disclosure, claims 1, 4, and 11 recite a “flexible shaft” and “a plurality of elastically deformable blades” **where the plurality of elastically deformable blades can cut material in a space when the blades not deformed, after accessing the space through a passage while the blades are deformed.**” Applicants respectfully submit that claims 1, 4, 9, 11, 15, and 16 are therefore patentable over Middleton. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

Applicants respectfully traverse the rejection of claims 10 and 17 under 35 U.S.C. 103(a) as being unpatentable over Middleton as applied to claims 4 and 11 above in further view of U.S. Patent No. 6,248,110 to Reiley (“Reiley”).<sup>1</sup> To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490

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<sup>1</sup> Applicants respectfully note that the Office Action cites U.S. Patent No. 5,792,015 “to Scribner *et al*” rather than Reiley throughout the remainder of the rejection. U.S. Patent No. 5,792,015 is actually issued to Hoyt, *et. al.* and is directed to golf putting aides. Scribner, *et al.*, is U.S. Patent No. 5,972,015. It is not clear why Reilly is cited in the first paragraph of the rejection, but then Scribner, not Reily, is cited in the remaining portions of the rejection. Applicants respectfully request clarification in this regard. Applicants assume all references in the Office Action to “Scribner” or “U.S. Patent No. 5,792,015” mean Reiley (U.S. Patent No. 6,248,110). Regardless of whether the Action intends to rely on Reiley or Scribner, the rejection fails to render obvious the present claims because the primary reference to Middleton fails to disclose or suggest all of the elements of claims 4 and 11, from which the rejected claims depend.

F.2d 981, 180 USPQ 580 (CCPA 1974). Middleton and Reiley do not teach or suggest all the limitations recited by claims 10 and 17 either alone or in combination.

As discussed above, Middleton teaches a cavitation device. Middleton does not teach a device with a flexible shaft and a plurality of deformable blades. Reiley teaches a method of treating bones using expandable bodies including a conventional, rigid spinal needle assembly. As a result, Reiley does not overcome Middleton's deficiencies. Applicants respectfully submit that claims 10 and 17 are therefore patentable over Middleton in view of Reiley. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

Respectfully submitted,

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By ELEANOR M. HYNES

GOODWIN PROCTER LLP  
901 New York Avenue, NW  
Washington, DC 20001  
Telephone: 202-346-4000  
Facsimile: 202-346-4444

ELEANOR M. HYNES  
Attorney for Applicant  
Registration No. 58,013  
[ehynes@goodwinprocter.com](mailto:ehynes@goodwinprocter.com)

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